

FOREWORD

The Office of Regulatory Affairs has a critical role in maintaining the Agency's recognition as the nation's premier consumer protection Agency. I personally seek to create and foster an environment that supports excellence. Towards this end, I strongly believe that each one of us is personally accountable for maintaining the excellent reputation of ORA. It is my firm desire to ensure that ORA laboratories are state-of-the-art and are founded on a strong, science-based Quality Management System.

Sample collection and laboratory analysis is an important and critical part of FDA's regulatory activities. A valid sample is the starting point for most administrative and legal actions. Therefore, as evidence, the sample must be suitable to support FDA's charge that there has been a violation of the Act.

The Laboratory Manual (LM) is the primary source for communicating to our laboratory staff the manner in which business is to be conducted within a regulatory framework while carrying out the Agency's public health mission. It provides the standard against which work products should be measured and spells out the laboratory objectives for ISO 17025 accreditation. Adherence to this manual by ORA laboratory staff is paramount to ensuring quality, consistency, and efficiency throughout the field. Although the LM is ORA's primary resource for laboratory information, other manuals and directives may supplement specific topics. Recognizing that the LM may not cover all situations and variables arising from the laboratory setting, any significant departures must have the concurrence of management and must be appropriately documented.

ORA is committed to the continuous improvement of the LM as we seek to maintain and foster excellence in our daily laboratory operations.

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Regulatory Affairs